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1762
PATENT

Atty. Docket No. DX0261K1Q

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Jeffrey Gillis

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maria-Grazia RONCAROLO, et al.

Serial No.:

09/718,102

Filed:

11/20/00

For:

USE OF INTERLEUKIN-10 TO

PRODUCE A POPULATION OF

SUPPRESSOR CELLS

Examiner: not yet assigned

Art Unit:

1762

INFORMATION DISCLOSURE STATEMENT

Palo Alto, California 94304

January 28, 2002

RECEIVED
TO 1700

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The materials as listed in the attached modified PTO 1449 form are brought to the Examiner's attention pursuant to the duty of disclosure under 37 C.F.R. § 1.56, § 1.97, and § 1.98.

Copies of all references except references Al and BD, have been included in the Information Disclosure Statement for one parent file, U.S.S.N. 08/643,810, filed May 6, 1996, Attorney Docket No. DX0261K1, and should be available there.

Copies of newly cited references AI and BD are attached hereto.

Citation of these documents should not be construed as a representation that the documents are in fact material or are in fact prior art with respect to the instant invention. The Examiner should not make any inference relating to the relative pertinence of cited references based upon the order in which the art is presented. Citation of these documents should not be construed as a representation that a search has been made or that more pertinent art may not be in existence.

Applicants request that the Examiner fully consider the art cited in the attached modified PTO 1449 form. Applicants further request that the Patent and Trademark Office list all such art on the front of any patent issuing from this application.

Since this Information Disclosure Statement is being filed before receiving the first Office action, applicants believe no fee is required for filing this document; however, if such a fee is required the Commissioner is hereby authorized to charge DNAX Research Institute's Deposit Account No. 04-1239.

January 28, 2002

Respectfully submitted,

Sheela Mohan-Peterson Attorney for Applicants

Reg. No. 41,201

Enclosures:

Modified PTO 1449 form (4 pages)

References AI and BD (2 refs.)

DEPARTMENT OF COMMERCE ATTY, DOCKET SERIAL NO. FOR PATENT

OTHER DOCUMENTS (Incl.

BG "Two "Two "Two "Trademai reademai re TENT AND TRADEMARK OFFICE DX0261K1Q 09/718,102 CLOSURE STATEMENT APPLICANT: Maria-Grazia RONCAROLO, et al. FILING DATE: GROUP: 11/20/00 1762 HER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) David F. Fiorentino, et al., J. Exp. Med. 170:2081-2095, December 1989. "Two Types of Mouse T Helper Cell: IV. Th2 Clones Secrete a Factor that Inhibits Cytokine David F. Fiorentino, et al. J. Immunol. 146:3444-3451, May 1991. BH "IL-10 Acts on the Antigen-Presenting Cell to Inhibit Cytokine Production by Th1 Cells" Stephen J. Forman, et al., Bone Marrow Transplantation, Blackwell Scientific Publications. В Cambridge, MA, Chapter 4, verso and pp. 37-38, 1994. James D. Fraser, et al., Immunol. Today 14:357-362, 1993. BJ "Signal Transduction Events Leading to T-Cell Lymphokine Gene Expression" Arnold S. Freedman, et al., J. Immunol. 139:3260-3267, November 1987. BK "B7, a B Cell-Restricted Antigen that Identifies Preactivated B Cells" Ricardo T. Gazzinelli, et al., J. Immunol. 148:1792-1796, 1992. BL "IL-10 Inhibits Parasite Killing and Nitrogen Oxide Production by IFN-g-Activated Macrophges" Ning Fei Go, et al., J. Exp. Med. 172:1625-1631, December 1990. ВМ "Interleukin 10, a Novel B Cell Stimulatory Factor: Unresponsiveness of X Chromosome-Linked Immunodeficiency B Cells" Hervé Groux, et al., J. Exp. Med. 184:19-29, July 1996. ΒN "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4+ T Cells" Clifford V. Harding, et al., Proc. Natl. Acad Sci. 87:5553-5557, July 1990. ВО "Functional and Ultrastructrual Evidence for Intracellular Formation of Major Histocmpatibility Complex Class II-Peptide Complexes during Antigen Processing" Chyi-Song Hseih, et al., Science 260:547-549, April 1993. BP "Development of Th1 CD4+ T Cells through IL-12 Produced by Listeria-Induced Macrophages" Di-Hwei Hsu, et al., Science, 250:830-832, Nov. 1990. BQ "Expression of Interleukin-10 Activity by Epstein-Barr Virus Protein BCRFI" Marc K. Jenkins, Immunol. Today 13:69-73, 1992. BR "The Role of Cell Division in the Induction of Clonal Anergy" Marc Jenkins, et al., J. Immunol. 144:16-22, January 1, 1990. BS "Inhibition of Antigen-Specific Proliferation of Type 1 Murine T Cell Clones after Stimulation with Immobilized Anti-CD3 Monoclonal Antibody" Sang-Mo Kang, et al., Science 257:1134-1138, August 21, 1992. ВТ "Transactivation by AP-1 Is a Molecular Target of T Cell Clonal Anergy" Jonathan R. Lamb, et al., J. Exp. Med. 157 1434-1447, May 1983. BU "Induction of Tolerance in Influenza Virus-Immune T Lymphocyte Clones with Synthetic Peptides of Influcenza Hemagglutinin" Wei Li, et al., Science 271:1272-1276, March 1, 1996. BV "Blocked Signal Transduction to the ERK and JNK Protein Kinases in Anergic CD4+ T Cells" Steven E. Macatonia, et al., "Differential Effect of IL-10 on Dendritic Cell-Induced T Cell Proliferation and IFN-γ Production" <u>J. Immunol.</u> 150:3755-3765, May 1, 1993. BW Keven W. Moore, et al., Science 248:1230-1234, June 1990. BX "Homology of Cytokine Synthesis Inhibitory Factor (IL-10) to the Epstein-Barr Virus Gene BCRFI" Hiroaki Niiro, et al., Intl. Immunol. 6:661-664, 1994. BY "IL-10 Inhibits Prostaglandin E2 Production by Lypopolysaccharide-Stimulated Monocytes" William E. Paul, ed., Fundamental Immunology, 2nd ed., Raven Press, NY, title page, verso, ΒZ Chapter 1 pp. 15-16, 1989. EXAMINER DATE CONSIDERED

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO .: SERIAL NO PATENT AND TRADEMARK OFFICE DX0261K1Q 09/718,102 IN FROM ATION DISCLOSURE STATEMENT APPLICANT Maria-Grazia RONCAROLO, et al. FOR PATENT FILING DATE: GROUP: higs several sheets if necessary) 11/20/00 1762 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Ligia M. T. Peçanha, et al., J. Immunol. 150:3215-3233, April 15, 1993. "IL-10 Inhibits T Cell-Independent but Not T Cell-Dependent Responses in Vitro" Josette Péguet-Navarro, et al., Er. J. Immunol. 24:884-891, 1994. "Interleukin-10 Inhibits the Primary Allogenic T Cell Response to Human Epidermal Langerhans Fred Ramsdell, et al., Science 257:1130-1134, August 21, 1994. CC "Maintenance of in Vivo Tolerance by Persistence of Antigen" Han-Jurgen Rode, et al., Virus Genes 7:111-116, 1993. CD "The Genome of Equine Herpesvirus Type 2 Harbors an Interleukin 10 (IL-10)-Like Gene" Maria-Grazia Roncarolo, et al., Bone Marrow Transplantation: Proceedings of Fetal and Neonatal CE Cell Transplantation and Retroviral Gene Therapy, Vol. 9, Supp. 1:127-128, 1992. "T Cell Repertoire and Tolerance After Fetal Stem Cell Transplantation" Maria-Grazia Roncarolo, et al., Journal of Cellular Biochemistry, supp. 16A:214, 1992. CF "SCID Patients Reconstituted by Fetal Liver Stem Cells: Possible Role of IL-10 in Transplantation Tolerance" Maria Grazia Roncarolo, et al., J. Exp. Med. 167:1523-1534, May 1988. CG "Alloreactive T Cell Clones Specific for Class I and Class II HLA Antigens Isoated from a Human Chimera" Ronald H. Schwartz, Science 248:1349-1356, June 15, 1990. СН "A Cell Culture Model for T Lymphocyte Clonal Anergy" RECEIVED
TC. 1700 Hergen Spits, et al., Int. Arch. Allergy Immunol. 99:8-15, 1992. CI "Functional Characterization of Human IL-10" Gen Suzuki, et al., Int'l. Immunol. 7:37-43, 1995. CJ "Impaired CD-28-Mediated Co-Stimulation in Anergic T Cells" Kazuyuki Taga, et al., Blood 81:2964-2971, June 1, 1993. CK "Human Interleukin-10 Can Directly Inhibit T-Cell Growth" Shingo Takanaski, et al., J. Exp. Med. 180:711-715, August 1994. CL "Interleukin 10 Inhibits Lipopolysaccharide-Induced Survival and Cytokine Production by Human Peripheral Blood Eosinophils" Bart A. E. Vandekerckhove, et al., J. Exp. Med. 175:1033-1043, April 1992. CM "Human Hematopoietic Cells and Thymic Epithelial Cells Induce Tolerance via Different Mechanisms in the SCID-hu Mouse Thymus" P. Vieira, et al., Proc. Natl. Acad. Sci. 88:1172-1176, Feb. 1991. CN "Isolation and Expression of Human Cytokine Synthesis Inhibitory Factor cDNA Clones: Homology to Epstein-Barr Virus Open reading Frame BCRFI" R. Weimer, et al. Transplantation, 62(11):1606-1614, 1996. CO "Pretransplant CD4 Helper Function and Interleukin 10 Response Predict Risk of Acute Kidney Graft Rejection" Fabienne Williams, et al., Eur. J. Immunol. 24:1007-1009, 1994. CP "Interleukin-10 Inhibits B7 and Intercellular Adhesion Molecule-1 Expression on Human Monocytes" Hans Yssel, et al., J. Immunol. 149:2378-2384, October 1, 1992. CQ "IL-10 Is Produced by Subsets of Human CD4+ T Cell Clones and Peripheral Blood T Cells" **EXAMINER** DATE CONSIDERED

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